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510(k) SUMMARY

Guided Growth System
Stainless Steel eight-Plate/quad-Plate

JUN 2 1 2011

Summary Date:	March 7, 2011
Submitter Data:	Orthofix Inc. 3451 Plano Parkway Lewisville, TX 75656 214-937-2000 214-937-2764 (fax)
Primary Contact:	Darla Chew darlachew@orthofix.com
Device Trade Name:	Guided Growth System – stainless steel eight-Plate/quad-Plate
Common Name:	bone plate
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories. (21 CFR Parts 888.3030
Product Code:	OBT – plate, bone, growth control, pediatric, epiphysiodesis
Legally Marketed Predicate Devices:	Growth Guidance Plate (eight-Plate) K031439/ 11-20-03 Guided Growth System (quad-Plate) K093442/ 06-10-10
Device Description:	The Guided Growth System is designed for the gradual correction of pediatric deformities in both the upper and lower extremities. The device can be used for correction of congenital and acquired deformities provided that the physis (growth plates) are not fused. The plates feature a contoured waist and low profile for pediatric usage. There is a center hole in the plate for a temporary guide pin to be implanted to ensure accurate application of the plate. The plates are attached to the external surface of the bone over the growth plate by two or four screws. These screws are not locked to the plate, but rather are allowed to swivel and diverge in their position as bone growth occurs. The implant acts like a flexible hinge, permitting growth at the growth plate to gradually straighten the limb. Immediately after implantation, the patient is allowed mobility and weight bearing. The plates and screws are made from implant quality stainless steel conforming to ASTM F-138.
Indications for Use:	The Guided Growth System plates are designed for the express and sole purpose of redirecting the angle of growth of long bone(s). This is useful for gradually correcting angular deformities in growing children. Specific conditions/diseases for which the device will be indicated include: valgus, varus or flexion, extension deformities of the knee (femur and/or

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tibia),valgus, varus or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow (humerus), radial or ulnar deviation, flexion or extension deformities of the wrist (radius).

Biomechanical Testing:

In order to demonstrate that the Stainless steel Guided Growth System has the mechanical properties necessary to perform its intended use and to perform as well as the predicate device, Orthofix conducted mechanical and functional testing of the system. This testing includes tensile strength testing and stiffness calculations. The results of the testing demonstrated the Stainless Steel Guided Growth System to meet or exceed all testing requirements and to perform as well as the predicate device.

Technological Characteristics:

The Stainless Steel Guided Growth System is considered to be substantially equivalent in design, intended use and material to the predicate device. However, there are certain design differences, but these do not raise new questions regarding safety and effectiveness.

Features	**Guided Growth System – Stainless Steel**
Plate/Screw Material	Implant quality stainless steel (316L)
Available Plate Sizes	eight-Plate: 12mm; 16mm quad-Plate: 16mm; 22mm
Plate Geometry	Contoured waist and low profile for pediatric usage. Center hole for a temporary guide pin to ensure accurate application of the plate.
Fixation Method, Screw Holes	Plates are attached to the external surface of the bone over the growth plate by bone screws two (eight-Plate) or four (quad-Plate)
Screw Type	Cannulated or Solid
Screw Length	16mm – cannulated 24mm and 32mm – cannulated and solid

Sterilization:

The stainless steel Guided Growth System components are supplied NON-STERILE and require sterilization prior to use.

Substantial Equivalence:

Substantial equivalence is based upon design, dimension, material characterization, and biomechanical testing of the device in comparison to the predicates. The stainless steel Guided Growth System is substantially equivalent in design and function to the Growth Guidance Plate – eight-Plate (K031493 / 11/20/03) and the Guided Growth System – quad-Plate (K093442 / 06/10/10)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Orthofix Inc.
% Ms. Mary Biggers
Regulatory Consultant
3451 Plano Parkway
Lewisville, Texas 75056

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Re: K110805
Trade/Device Name: Orthofix Guided Growth System eight-Plate/quad-stainless steel (pediatric epiphysiodesis bone plates)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: OBT
Dated: June 7, 2011
Received: June 9, 2011

Dear Ms. Biggers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

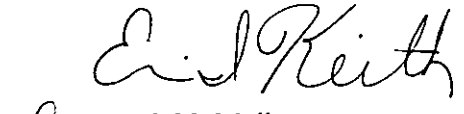
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110805

INDICATION FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: **Orthofix Guided Growth System eight-Plate/quad-Plate – stainless steel (pediatric epiphysiodesis bone plates)**

Indications for Use:

The Guided Growth Plates are designed for the express and sole purpose of redirecting the angle of growth of long bone(s). This is useful for gradually correcting angular deformities in growing children. Specific conditions/diseases for which the device will be indicated include: valgus, varus or flexion; extension deformities of the knee (femur and/or tibia),valgus, varus or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow (humerus), radial or ulnar deviation, flexion or extension deformities of the wrist (radius).

Prescription Use: X Or Over-The-Counter__ __ __
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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